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| **DETAILS OF ASSESSMENT** | |
| **ORGANISATION** |  |
| **LABORATORY REFERENCE NUMBER** |  |
| **TYPE OF ASSESSMENT** | **Preliminary visit Initial Assessment**  **Assessment Extension**  **Extraordinary visit Re-assessment**  *(Specify:…………………………….)* |
| **LABORATORY REPRESENTATIVE** |  |
| **DOCUMENTATION USED** | **Quality Manual Procedures Manual**  **Work Instructions Records**  **Standard Operating Procedures** |
| **NAME OF ASSESSOR/ MAURITAS STAFF** |  |
| **SIGNATURE** |  |
| **DATE OF REVIEW** |  |
| **DATE(S) OF ASSESSMENT** |  |

***NOTE: 1****. Compliance = C, Non-compliance = NC, Not Applicable =NA*

**2. MAURITAS R DOCUMENTS REQUIREMENTS**

***Assessors need to check conformance of the laboratory with respect to the requirements of MAURITAS R3 and R4 Regulations:***

**MAURITAS R3 – Traceability of measurement**

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| **CLAUSE** | **MAURITAS R3 REQUIREMENT** | **C/NC/NA** | **EVIDENCE CHECKED** |
| **6.1-6.2** | Assessor/MS to check whether:  (i) calibrations are performed by an NMI covered by the CIPM MRA; |  |  |
| or (ii) an accredited calibration laboratory covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC; |  |  |
| or (iii) an accredited NMI |  |  |
| **6.3** | Assessor/MS to check whether:   1. CRMs are produced by NMIs using a service that is included in the BIPM KCDB; |  |  |
|  | 1. CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC. |  |  |
|  | 1. Where CRMs are produced by non-accredited RMPs, Accredited/applicant laboratories shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use |  |  |
| **6.4** | Assessor to check whether laboratory performs in-house calibrations. |  |  |
| **7.2** | Assessor/MS to check CMC calculations (for calibration laboratories only). |  |  |

**MAURITAS R4 – Conditions for the Use of MAURITAS accreditation symbol**

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| **CLAUSE** | **MAURITAS R4 REQUIREMENT** | **C/NC/NA** | **EVIDENCE CHECKED** |
| **5 & 6** | Assessor/MS to check the use of MAURITAS symbol/Combined Mark /disclaimer on test/calibration report; |  |  |
| **6.10.2.3** | Assessor/MS to check the use of disclaimers when the laboratory makes use of opinions and interpretations. |  |  |
| **6.10.2.4** | Assessor to check calibration labels affixed on equipment after calibration (for calibration laboratories only) |  |  |

**3. REVIEW: ISO/IEC 17025:2017**

| **CLAUSE** | **TECHNICAL REQUIREMENTS** | **C/NC/**  **NA** | **EVIDENCE CHECKED** |
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| **6** | **Resources requirements** |  |  |
| **6.1** | **General** |  |  |
|  | Does the laboratory have the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities? |  |  |
| **6.2** | **Personnel** |  |  |
| **6.2.1** | Do all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially? Are they competent and do they work in accordance with the laboratory’s management system? |  |  |
| **6.2.2** | Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience? |  |  |
| **6.2.3** | Does the laboratory ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations? |  |  |
| **6.2.4** | Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities? |  |  |
| **6.2.5** | Does the laboratory have procedure(s) and retain records for:   1. determining the competence requirements; 2. selection of personnel; 3. training of personnel; 4. supervision of personnel; 5. authorization of personnel; 6. monitoring of competence of personnel? |  |  |
| **6.2.6** | Does the laboratory authorise its personnel to perform specific laboratory activities, including but not limited to, the following:   1. development, modification, verification and validation of methods; 2. analysis of results, including statements of conformity or opinions and interpretations; 3. report, review and authorization of results. |  |  |
| **6.3** | **Facilities and environmental conditions** |  |  |
| **6.3.1** | Are the facilities and environmental conditions suitable for the laboratory activities and do they adversely affect the validity of results? |  |  |
| **6.3.2** | Are the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities documented? |  |  |
| **6.3.3** | Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results? |  |  |
| **6.3.4** | Are measures to control facilities implemented, monitored and periodically reviewed?  Does this include, but not be limited to:   1. access to and use of areas affecting laboratory activities; 2. prevention of contamination, interference or adverse influences on laboratory activities; 3. effective separation between areas with incompatible laboratory activities? |  |  |
| **6.3.5** | When the laboratory performs laboratory activities at sites or facilities outside its permanent control, does it ensure that the requirements related to facilities and environmental conditions of this document are met? |  |  |
| **6.4** | **Equipment** |  |  |
| **6.4.1** | Does the laboratory have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result? |  |  |
| **6.4.2** | In those cases where the laboratory uses equipment outside its permanent control, does it ensure that the requirements for equipment of this document are met? |  |  |
| **6.4.3** | Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration? |  |  |
| **6.4.4** | Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service? |  |  |
| **6.4.5** | Is the equipment used for measurement capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result? |  |  |
| **6.4.6** | Are measuring equipment calibrated when:   * the measurement accuracy or measurement uncertainty affects the validity of the reported results, or * calibration of the equipment is required to establish the metrological traceability of the reported result? |  |  |
| **6.4.7** | Does the laboratory establish a calibration programme, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? |  |  |
| **6.4.8** | Is all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity? |  |  |
| **6.4.9** | Is equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service?  Is it isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly? |  |  |
| **6.4.9** | Does the laboratory examine the effect of the defect or deviation from specified requirements and does it initiate the management of nonconforming work procedure? (refer to 7.10) |  |  |
| **6.4.10** | When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks carried out according to a procedure? |  |  |
| **6.4.11** | When calibration and reference material data include reference values or correction factors, does the laboratory ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements? |  |  |
| **6.4.12** | Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results? |  |  |
| **6.4.13** | Are records retained for equipment which can influence laboratory activities?  Do the records include the following, where applicable:   1. the identity of equipment, including software and firmware version; 2. the manufacturer’s name, type identification, and serial number or other unique identification; |  |  |
| **6.4.13** | 1. evidence of verification that equipment conforms with specified requirements; 2. the current location; 3. calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval; 4. documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity; 5. the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; 6. details of any damage, malfunction, modification to, or repair of, the equipment? |  |  |
| **6.5** | **Metrological traceability** |  |  |
| **6.5.1** | Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? |  |  |
| **6.5.2** | Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) through one of the following:   1. calibration provided by a competent laboratory; 2. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; 3. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards? |  |  |
| **6.5.3** | When metrological traceability to the SI units is not technically possible, does the laboratory demonstrate metrological traceability to an appropriate reference, e.g.   1. certified values of certified reference materials provided by a competent producer; |  |  |
| **6.5.3** | 1. results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison? |  |  |
| **7** | **Process requirements** |  |  |
| **7.2** | **Selection, verification and validation of methods** |  |  |
| **7.2.1** | **Selection and verification of methods** |  |  |
| **7.2.1.1** | Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data? |  |  |
| **7.2.1.2** | Areall methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and are made readily available to personnel? |  |  |
| **7.2.1.3** | Does the laboratory ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so?  When necessary, is the application of the method supplemented with additional details to ensure consistent application? |  |  |
| **7.2.1.4** | When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen?  Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used. |  |  |
| **7.2.1.5** | Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance?  Are records of the verification retained?  If the method is revised by the issuing body, is verification repeated to the extent necessary? |  |  |
| **7.2.1.6** | When method development is required, is this a planned activity and assigned to competent personnel equipped with adequate resources?  As method development proceeds, are periodic review carried out to confirm that the needs of the customer are still being fulfilled? |  |  |
| **7.2.1.6** | Are any modifications to the development plan approved and authorized? |  |  |
| **7.2.1.7** | Are deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer? |  |  |
| **7.2.2** | **Validation of methods** |  |  |
| **7.2.2.1** | Does the laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified?  Is the validation as extensive as is necessary to meet the needs of the given application or field of application?  Note: The techniques used for method validation can be one of, or a combination of, the following:   1. calibration or evaluation of bias and precision using reference standards or reference materials; 2. systematic assessment of the factors influencing the result; |  |  |
|  |  |
| **7.2.2.1** | 1. testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; 2. comparison of results achieved with other validated methods; 3. interlaboratory comparisons; 4. evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method? |  |  |
| **7.2.2.2** | When changes are made to a validated method, are the influence of such changes determined and where they are found to affect the original validation, is a new method validation performed? |  |  |
| **7.2.2.3** | Are the performance characteristics of validated methods as assessed for the intended use, relevant to the customers’ needs and consistent with specified requirements? |  |  |
| **7.2.2.4** | Does the laboratory retain the following records of validation:   1. the validation procedure used; 2. specification of the requirements; 3. determination of the performance characteristics of the method; 4. results obtained; 5. a statement on the validity of the method, detailing its fitness for the intended use? |  |  |
| **7.3** | **Sampling** |  |  |
| **7.3.1** | Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration?  Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results?  Is the sampling plan and method available at the site where sampling is undertaken?  Are sampling plans, whenever reasonable, based on appropriate statistical methods? |  |  |
| **7.3.2** | Does the sampling method describe:   1. the selection of samples or sites; 2. the sampling plan; 3. the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration? |  |  |
| **7.3.3** | Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken?  Do these records include, where relevant:   1. reference to the sampling method used; 2. date and time of sampling; 3. data to identify and describe the sample (e.g. number, amount, name); 4. identification of the personnel performing sampling; 5. identification of the equipment used; 6. environmental or transport conditions; 7. diagrams or other equivalent means to identify the sampling location when appropriate; 8. deviations, additions to or exclusions from the sampling method and sampling plan? |  |  |
| **7.4** | **Handling of test or calibration items** |  |  |
| **7.4.1** | Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer?  Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration?  Are handling instructions provided with the item followed? |  |  |
| **7.4.2** | Does the laboratory have a system for the unambiguous identification of test or calibration items?  Is the identification retained while the item is under the responsibility of the laboratory? |  |  |
| **7.4.2** | Does the system ensure that items will not be confused physically or when referred to in records or other documents?  Does the system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items? |  |  |
| **7.4.3** | Upon receipt of the test or calibration item, are deviations from specified conditions recorded?  When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding?  Does the laboratory record the results of this consultation?  When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation? |  |  |
| **7.4.4** | When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded? |  |  |
| **7.5** | **Technical records** |  |  |
|  | Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? |  |  |
| **7.5.1** | Do the technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? |  |  |
| **7.5.1** | Are original observations, data and calculations recorded at the time they are made and are identifiable with the specific task? |  |  |
| **7.5.2** | Does the laboratory ensure that amendments to technical records can be tracked to previous versions or to original observations?  Are both the original and amended data and files kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations? |  |  |
| **7.6** | **Evaluation of measurement uncertainty** |  |  |
| **7.6.1** | Do laboratories identify the contributions to measurement uncertainty?  When evaluating measurement uncertainty, are all contributions which are of significance, including those arising from sampling, taken into account using appropriate methods of analysis? |  |  |
| **7.6.2** | Do laboratory performing calibrations, including of its own equipment, evaluate the measurement uncertainty for all calibrations. |  |  |
| **7.6.3** | Does the laboratory performing testing, evaluate measurement uncertainty?  Where the test method precludes rigorous evaluation of measurement uncertainty, is an estimation made based on an understanding of the theoretical principles or practical experience of the performance of the method? |  |  |
| **7.7** | **Ensuring the validity of results** |  |  |
| **7.7.1** | Does the laboratory have a procedure for monitoring the validity of results?  Is the resulting data recorded in such a way that trends are detectable and, where practicable?  Are statistical techniques applied to review the results? |  |  |
| **7.7.1** | Is this monitoring planned and reviewed and include, where appropriate, but not be limited to:   1. use of reference materials or quality control materials; 2. use of alternative instrumentation that has been calibrated to provide traceable results; 3. functional check(s) of measuring and testing equipment; 4. use of check or working standards with control charts, where applicable; 5. intermediate checks on measuring equipment; 6. replicate tests or calibrations using the same or different methods; 7. retesting or recalibration of retained items; 8. correlation of results for different characteristics of an item; 9. review of reported results; 10. intralaboratory comparisons; 11. testing of blind sample(s)? |  |  |
| **7.7.2** | Does The laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate?  Is this monitoring planned and reviewed and include, but not be limited to, either or both of the following:   1. participation in proficiency testing; 2. participation in interlaboratory comparisons other than proficiency testing? |  |  |
| **7.7.3** | Are data from monitoring activities analysed, used to control and, if applicable, improve the laboratory’s activities?  If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, is appropriate action taken to prevent incorrect results from being reported? |  |  |
| **7.8** | **Reporting of results** |  |  |
| **7.8.1** | **General** |  |  |
| **7.8.1.1** | Are the results reviewed and authorized prior to release? |  |  |
| **7.8.1.2** | Are the results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used?  Are all issued reports retained as technical records? |  |  |
| **7.8.1.3** | When agreed with the customer, the results may be reported in a simplified way. Are any information listed in 7.8.2 to 7.8.7 that is not reported to the customer readily available? |  |  |
| **7.8.2** | **Common requirements for reports (test, calibration or sampling)** |  |  |
| **7.8.2.1** | Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:   1. a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”); 2. the name and address of the laboratory;   **c)** the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities; |  |  |
| **7.8.2.1** | 1. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; 2. the name and contact information of the customer; 3. identification of the method used; 4. a description, unambiguous identification, and, when necessary, the condition of the item; 5. the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; 6. the date(s) of performance of the laboratory activity; 7. the date of issue of the report; 8. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; 9. a statement to the effect that the results relate only to the items tested, calibrated or sampled; 10. the results with, where appropriate, the units of measurement; |  |  |
|  | 1. additions to, deviations, or exclusions from the method; 2. identification of the person(s) authorizing the report; 3. clear identification when results are from external providers?   Does the laboratory include a statement specifying that the report should not be reproduced except in full, without approval of the laboratory? |  |  |
| **7.8.2.2** | Is the laboratory responsible for all the information provided in the report, except when information is provided by the customer?  Are data provided by a customer clearly identified?  In addition, is a disclaimer put on the report when the information is supplied by the customer and can affect the validity of results?  Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), does it state in the report that the results apply to the sample as received? |  |  |
| **7.8.3** | **Specific requirements for test reports** |  |  |
| **7.8.3.1** | In addition to the requirements listed in 7.8.2, are test reports, where necessary for the interpretation of the test results, include the following:   1. information on specific test conditions, such as environmental conditions; 2. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); 3. where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:  * it is relevant to the validity or application of the test results; * a customer’s instruction so requires, or * the measurement uncertainty affects conformity to a specification limit  1. where appropriate, opinions and interpretations (see 7.8.7);   **e)** additional information which may be required by specific methods, authorities, customers or groups of customers? |  |  |
| **7.8.3.2** | Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? |  |  |
| **7.8.4** | **Specific requirements for calibration certificates** |  |  |
| **7.8.4.1** | In addition to the requirements listed in 7.8.2, do calibration certificates include the following:   1. the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); 2. the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; 3. a statement identifying how the measurements are metrologically traceable (see Annex A of the standard); 4. the results before and after any adjustment or repair, if available; 5. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); 6. where appropriate, opinions and interpretations (see 7.8.7) |  |  |
| **7.8.4.2** | Where the laboratory is responsible for the sampling activity, do the calibration certificates meet the requirements listed in 78.5 where necessary, for the interpretation of calibration results? |  |  |
| **7.8.4.3** | Do the calibration certificate or calibration label contain any recommendation on the calibration interval, except where this has been agreed with the customer? |  |  |
| **7.8.5** | **Reporting sampling – specific requirements** |  |  |
| **7.8.5** | Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results:   1. the date of sampling; 2. unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); 3. the location of sampling, including any diagrams, sketches or photographs; 4. a reference to the sampling plan and sampling method; 5. details of any environmental conditions during sampling that affect the interpretation of the test results; 6. information required to evaluate measurement uncertainty for subsequent testing or calibration? |  |  |
| **7.8.6** | **Reporting statements of conformity** |  |  |
| **7.8.6.1** | When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule? |  |  |
| **7.8.6.2** | Does the laboratory report on the statement of conformity, such that the statement clearly identifies:   1. to which results the statement of conformity applies; 2. which specifications, standards or parts thereof are met or not met; 3. the decision rule applied (unless it is inherent in the requested specification or standard)? |  |  |
| **7.8.7** | **Reporting opinions and interpretation** |  |  |
| **7.8.7.1** | When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement?  Does the laboratory document the basis upon which the opinions and interpretations have been made? |  |  |
| **7.8.7.2** | Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and clearly identified as such? |  |  |
| **7.8.7.3** | When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue retained? |  |  |
| **7.8.8** | **Amendments to reports** |  |  |
| **7.8.8.1** | When an issued report needs to be changed, amended or re-issued, is any change of information clearly identified and, where appropriate, the reason for the change included in the report? |  |  |
| **7.8.8.2** | Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording?  Do such amendments meet all the requirements of this document? |  |  |
| **7.8.8.3** | When it is necessary to issue a complete new report, is it uniquely identified and does it contain a reference to the original that it replaces? |  |  |

🗆**The Assessor/MS has performed review of the documentation of the laboratory prior to the assessment.**

**Verified by: Name:…………………………… Signature:…………………… Date:………………**